

Atty. Dkt. No. 028622-0102

**UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Bernd DORKEN, *et al.*

Title: CD19xCD3 SPECIFIC POLYPEPTIDES AND USES THEREOF

Appl. No.: 09/673,735

Filing Date: December 27, 2000

Examiner: Parithosh K. TUNGATURTHI

Art Unit: 1643

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §1.56**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 C.F.R. §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 C.F.R. §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 C.F.R. §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 C.F.R. §1.97(b), before the mailing date of the first Office Action on the merits.

**RELEVANCE OF EACH DOCUMENT**

The present application has a co-pending European application that was the subject of Opposition proceedings. Many of the claims in granted European Patent, EP 1 071 752 B1, are similar in scope to claims in the present application. During these Opposition proceedings a last submission was filed by the Opponent on December 19, 2005, and this submission and the references cited therein were not available to the European representative until December 29<sup>th</sup>, 2005. Accordingly, the references were obtained by Applicants after the US issue fee was paid in the instant application on December 23, 2005. The references cited by Opponent in their December 19, 2005, submission not already of record in the instant application are A3, A6, A7, and A9 on the attached Form PTO/SB/08. In order to make the record complete, Applicants also submit references cited by Applicants in the Opposition proceeding not already of record in the instant application. These references are A1-A2, A4-A5, A8, and A10-A14, on the attached Form PTO/SB/08.

At oral proceedings held on January 19, 2006, the Opposition Division of the European Patent Office rejected the Opposition and European Patent 1 071 752 B1 was maintained as granted.

All of the documents are in English.

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment,

to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date February 10, 2006

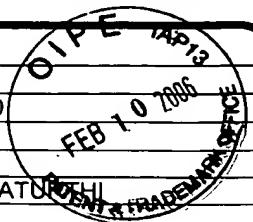
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Substitute for form 1449B/PTO				Complete if Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>					
Date Submitted: February 10, 2006 <i>(use as many sheets as necessary)</i>					
Sheet	1	of	2	Attorney Docket Number	028622-0102



### U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			

### U.S. PATENT APPLICATION DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Application Document		Name of Patentee or Applicant of Cited Document	Filing Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Serial Number	Kind Code <sup>2</sup> (if known)			

### FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	A1	EDELSTEIN, M.L., et al., "Gene Therapy Clinical Trials Worldwide: 1989-2004 – An Overview", <i>J. Gene Med.</i> , vol. 6, pp. 597-605 (2004).	
	A2	REUSCH, U., et al., "Effect of Tetravalent Bispecific CD19 X CD3 Recombinant Antibody Construct and CD28 Costimulation of Lysis of Malignant B Cells from Patients with Chronic Lymphocytic Leukemia by Autologous T Cells", <i>Int. J. Cancer</i> , vol. 112, pp. 509-518 (2004).	
	A3	LOFFLER, A., et al. "A Recombinant Bispecific Single-Chain Antibody, CD19 X CD3, Induces Rapid and High Lymphoma-directed Cytotoxicity by Unstimulated T Lymphocytes", <i>Blood</i> , vol. 95, no. 6, pp. 2098-2103 (2000).	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

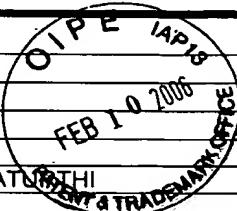
<sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

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Substitute for form 1449B/PTO				Complete if Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				Application Number	09/673,735
Date Submitted: February 10, 2006 <i>(use as many sheets as necessary)</i>				Filing Date	December 27, 2000
Sheet	2	of	2	First Named Inventor	Bernd DORKEN
				Group Art Unit	1643
				Examiner Name	Parithosh K. TUNGATHUTHI
				Attorney Docket Number	028622-0102



## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	A4	KIPRIYANOV, S.M., et al., "Bispecific Tandem Diabody for Tumor Therapy with Improved Antigen Binding and Pharmacokinetics", <i>J. Mol. Biol.</i> , vol. 293, pp. 41-56 (1999).	
	A5	HOLLIGER, P., et al., "Diabodies: Small Bispecific Antibody Fragments", <i>Cancer Immunol. Immunother.</i> , vol. 45, pp. 128-130 (1997).	
	A6	PEZZUTTO, A., et al., "CD19 Monoclonal Antibody HD37 Inhibits Anti-Immunoglobulin-induced B Cell Activation and Proliferation", <i>J. of Immunology</i> , vol. 138, no. 9, pp. 2793-2799 (1997).	
	A7	CSOKA, M., et al., "Activation of T Cell Cytotoxicity Against Autologous Common Acute Lymphoblastic Leukemia (cALL) Blasts by CD3 X CD19 Bispecific Antibody", <i>Leukemia</i> , vol. 10, pp. 1765-1772 (1996).	
	A8	DAVIS, B.M., et al., "Current Progress in the Gene Therapy of Cancer", <i>Current Opinion in Oncology</i> , vol. 8, pp. 499-508 (1996).	
	A9	KIPRIYANOV, S.M., et al. "Rapid Detection of Recombinant Antibody Fragments Directed Against Cell-surface Antigens by Flow Cytometry", <i>J. of Immunological Methods</i> , vol. 196, pp. 51-62 (1996).	
	A10	GRUBER, M., et al., "Efficient Tumor Cell Lysis Mediated by a Bispecific Single Chain Antibody Expressed in <i>Escherichia coli</i> ", <i>J. of Immunology</i> , vol. 152, pp. 5368-5374 (1994).	
	A11	HAYDEN, M.S., et al., "Single-chain Mono- and Bispecific Antibody Derivatives with Novel Biological Properties and Antitumour Activity from a COS Cell Transient Expression System", <i>Therapeutic Immunology</i> , vol. 1, pp. 3-15 (1994).	
	A12	WEINER, G.J., et al., "The Role of T Cell Activation in Anti-CD3 X Antitumor Bispecific Antibody Therapy", <i>J. of Immunology</i> , vol. 152, pp. 2385-2392 (1994).	
	A13	KOSTELNY, S.A., "Formation of a Bispecific Antibody by the Use of Leucine Zippers", <i>J. of Immunology</i> , vol. 148, no. 5, pp. 1547-1553 (1992).	
	A14	TRAUNECKER, A., et al. "JANUSIN: New Molecular Design for Bispecific Reagents", <i>Int. J. Cancer</i> , Suppl. 7, pp. 51-52 (1992).	

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<sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

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